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RELVAR(TM) ELLIPTA(TM) Receives Positive Opinion From the CHMP in Europe for the Treatment of Asthma and COPD

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 09/19/13 -- GlaxoSmithKline plc (NYSE: GSK) (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorisation for fluticasone furoate/vilanterol (FF/VI) under the proposed brand name RELVAR™ ELLIPTA™ for;

Asthma: the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta₂-agonist and inhaled corticosteroid) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta₂-agonists

COPD: the symptomatic treatment of adults with Chronic Obstructive Pulmonary Disease (COPD) with a FEV₁ < 70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy

Relvar is a combination of the inhaled corticosteroid (ICS) fluticasone furoate "FF" and the long-acting beta₂-agonist (LABA) vilanterol "VI". Two strengths of FF/VI are proposed for asthma (92/22 mcg and 184/22 mcg) and one strength is proposed for COPD (92/22 mcg). All strengths will be administered once-daily using the Ellipta, a new dry powder inhaler (DPI).

Patrick Vallance, GSK's President of Pharmaceuticals R&D, said: "Asthma and COPD are two of the most common respiratory conditions and affect millions of patients across Europe. GSK has been researching and developing these molecules as a potential new combination treatment for over ten years and today's opinion brings it one step closer to patients. What is particularly exciting is that we have achieved the first of what we hope in the future could be many positive regulatory outcomes supporting the potential use of FF/VI in appropriate patients with asthma. We eagerly await the final decision of the European Commission in the near future."

"This is another key milestone in over a decade of joint respiratory research and development between Theravance and GSK," said Rick E Winningham, Chief Executive Officer of Theravance. "We look forward to a number of important events during the remainder of 2013, including a final decision in Europe for FF/VI and the launch in the US for the treatment of COPD."

A CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission, but does not always result in marketing authorisation. A final decision by the European Commission is anticipated during the fourth quarter of 2013.

As part of its assessment, the EMA reviewed results of 11 clinical studies in 7,851 patients with COPD and 16 studies in 9,326 patients with asthma.

FF/VI 100/25 mcg was approved by the US Food and Drug Administration for use in patients with COPD in May 2013 under the trade name BREO™ ELLIPTA™. It was also approved for the treatment of COPD in Health Canada in July 2013 under the same trade name.

In Europe, the FF/VI doses of 92/22 mcg and 184/22 mcg are specified as the delivered doses (emitted from the inhaler). The lower strength is equivalent to the 100/25mcg pre-dispensed doses (contained inside the inhaler) approved in the US.

In September 2012, a regulatory submission for FF/VI under the trade name Relvar Ellipta was filed in Japan and is currently under review for asthma. FF/VI is not approved or licensed in the European Union or anywhere outside the US and Canada.

In the US, Breo Ellipta is not indicated for the relief of acute bronchospasm or the treatment of asthma. Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or [US Prescribing Information Breo Ellipta](#).

Important safety information for FF/VI in Europe

FF/VI is contraindicated in patients with hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

FF/VI should not be used to treat acute asthma symptoms or an acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a physician.

Patients should not stop therapy with FF/VI in asthma or COPD, without physician supervision since symptoms may recur after discontinuation.

Asthma-related adverse events and exacerbations may occur during treatment with FF/VI. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of treatment with FF/VI.

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a short-acting inhaled bronchodilator. FF/VI should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

Cardiovascular effects, such as cardiac arrhythmias e.g. supraventricular tachycardia and extrasystoles may be seen with sympathomimetic medicinal products including FF/VI. Therefore fluticasone furoate/vilanterol should be used with caution in patients with severe cardiovascular disease.

For patients with moderate to severe hepatic impairment, the 92/22 micrograms dose should be used and patients should be monitored for systemic corticosteroid-related adverse reactions. FF/VI 184/22 mcg is not indicated for patients with COPD. There is no additional benefit of the 184/22 mcg dose compared to the 92/22 mcg dose and there is a potential increased risk of pneumonia and systemic corticosteroid-related adverse reactions.

An increase in the incidence of pneumonia has been observed in subjects with COPD receiving FF/VI. There was also an increased incidence of pneumonias resulting in hospitalisation. In some incidences these pneumonia events were fatal.

The incidence of pneumonia in patients with asthma was common at the higher dose. The incidence of pneumonia in patients with asthma taking FF/VI 184/22 mcg was numerically higher compared with those receiving FF/VI 92/22 mcg or placebo.

Hyperglycaemia: There have been reports of increases in blood glucose levels in diabetic patients and this should be considered when prescribing to patients with a history of diabetes mellitus.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Oropharyngeal candidiasis has occurred in patients treated with FF/VI. FF/VI should be administered with caution in patients with pulmonary tuberculosis or in patients with chronic or untreated infections. Data from large asthma and COPD clinical trials were used to determine the frequency of adverse reactions associated with FF/VI. In the asthma clinical development program a total of 7,034 patients were included in an integrated assessment of adverse reactions. In the COPD clinical development programme a total of 6,237 subjects were included in an integrated assessment of adverse reactions.

Very common adverse reactions (occurring in > 1/10 patients) with FF/VI were headache and nasopharyngitis. Common adverse reactions (occurring in > 1/100 to < 1/10 patients) were pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures and pyrexia. Extrasystoles were observed as an uncommon adverse reaction (occurring in > 1/1,000 to < 1/100 patients). With the exception of pneumonia and fractures, the safety profile was similar in patients with asthma and COPD. During clinical studies, pneumonia and fractures were more frequently observed in patients with COPD.

Other respiratory development programmes:

In addition to FF/VI, the GSK respiratory development portfolio also includes LAMA/LABA (umeclidinium bromide (UMEC)/VI), with proposed brand name ANORO™ ELLIPTA™, VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

RELVAR™, BREQ™, ANORO™ and ELLIPTA™ are trademarks of GlaxoSmithKline group of companies. The use of the brand names Anoro and Relvar is not approved by any regulatory authorities.

GlaxoSmithKline -- one of the world's leading research-based pharmaceutical and healthcare companies -- is committed to

improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

Theravance -- is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programmes include: RELVAR™ ELLIPTA™ or BREO ELLIPTA™ (FF/VI), ANORO™ ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist/Beta₂ Agonist), GSK961081, each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist programme. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at www.theravance.com.

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GlaxoSmithKline cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

Theravance forward-looking statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Theravance intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates, statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights and statements concerning expectations for product candidates through development and commercialization and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Theravance as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance to be materially different from those reflected in its forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to delays or difficulties in commencing or completing clinical studies, the potential that results of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to develop and commercialize products. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 1, 2013 and the risks discussed in our other periodic filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements.

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